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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.  | CONFIRMATION NO. |
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[REDACTED] EXAMINER

STRZELECKA, TERESA E

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1637

12

DATE MAILED: 08/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

|  |                                 |                  |
|--|---------------------------------|------------------|
| <b>Office Action Summary</b>   | Application No.                 | Applicant(s)     |
|  | 10/067,543                      | BYRD ET AL.      |
|  | Examiner<br>Teresa E Strzelecka | Art Unit<br>1637 |
| -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  |                                 |                  |
| <b>Period for Reply</b>  |                                 |                  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  |                                 |                  |
| <ul style="list-style-type: none"> <li>- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.</li> <li>- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.</li> <li>- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.</li> <li>- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).</li> <li>- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).</li> </ul>   |                                 |                  |
| <b>Status</b>  |                                 |                  |
| <p>1)<input checked="" type="checkbox"/> Responsive to communication(s) filed on <u>10 April 2003</u>.</p> <p>2a)<input type="checkbox"/> This action is FINAL.                  2b)<input checked="" type="checkbox"/> This action is non-final.</p> <p>3)<input type="checkbox"/> Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i>, 1935 C.D. 11, 453 O.G. 213.</p>   |                                 |                  |
| <b>Disposition of Claims</b>   |                                 |                  |
| <p>4)<input checked="" type="checkbox"/> Claim(s) <u>1 and 3-57</u> is/are pending in the application.</p> <p>4a) Of the above claim(s) <u>7-12, 17-32, 36-53 and 55-57</u> is/are withdrawn from consideration.</p> <p>5)<input type="checkbox"/> Claim(s) _____ is/are allowed.</p> <p>6)<input checked="" type="checkbox"/> Claim(s) <u>1,3-6,13-16,34,35 and 54</u> is/are rejected.</p> <p>7)<input checked="" type="checkbox"/> Claim(s) <u>4</u> is/are objected to.</p> <p>8)<input type="checkbox"/> Claim(s) _____ are subject to restriction and/or election requirement.</p>   |                                 |                  |
| <b>Application Papers</b>  |                                 |                  |
| <p>9)<input type="checkbox"/> The specification is objected to by the Examiner.</p> <p>10)<input type="checkbox"/> The drawing(s) filed on _____ is/are: a)<input type="checkbox"/> accepted or b)<input type="checkbox"/> objected to by the Examiner.</p> <p style="margin-left: 20px;">Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).</p> <p>11)<input type="checkbox"/> The proposed drawing correction filed on _____ is: a)<input type="checkbox"/> approved b)<input type="checkbox"/> disapproved by the Examiner.</p> <p style="margin-left: 20px;">If approved, corrected drawings are required in reply to this Office action.</p> <p>12)<input type="checkbox"/> The oath or declaration is objected to by the Examiner.</p>  |                                 |                  |
| <b>Priority under 35 U.S.C. §§ 119 and 120</b>   |                                 |                  |
| <p>13)<input type="checkbox"/> Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</p> <p>a)<input type="checkbox"/> All    b)<input type="checkbox"/> Some * c)<input type="checkbox"/> None of:</p> <p style="margin-left: 20px;">1.<input type="checkbox"/> Certified copies of the priority documents have been received.</p> <p style="margin-left: 20px;">2.<input type="checkbox"/> Certified copies of the priority documents have been received in Application No. _____.</p> <p style="margin-left: 20px;">3.<input type="checkbox"/> Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</p> <p>* See the attached detailed Office action for a list of the certified copies not received.</p> <p>14)<input checked="" type="checkbox"/> Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).</p> <p>a)<input type="checkbox"/> The translation of the foreign language provisional application has been received.</p> <p>15)<input type="checkbox"/> Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.</p> |                                 |                  |
| <b>Attachment(s)</b>   |                                 |                  |
| <p>1)<input checked="" type="checkbox"/> Notice of References Cited (PTO-892)</p> <p>2)<input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</p> <p>3)<input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>8,9</u>.</p> <p>4)<input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____.</p> <p>5)<input type="checkbox"/> Notice of Informal Patent Application (PTO-152)</p> <p>6)<input type="checkbox"/> Other: _____.</p>   |                                 |                  |

**DETAILED ACTION**

***Election/Restrictions***

1. Applicant's election without traverse of Group I (claims 1, 3-6, 13-16, 34, 35 and 54) in Paper No. 11 is acknowledged.
2. Claims 7-12, 17-33, 36-53, 55-57 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 11.
3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Information Disclosure Statement***

4. The information disclosure statements (IDS) submitted on September 10, 2002 and November 21, 2003 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner.

***Claim Objections***

5. Claim 4 is objected to because of the following informalities: claim 4 depends from cancelled claim 2. Appropriate correction is required.
6. Claim 4 is objected to because of the following informalities: typographical error: tem-loop instead of stem-loop. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 34, 35 and 54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 34 and 35 are indefinite in claim 34, because claim 34 is indefinite over the recitation of “a linear nucleic acid molecule of claim 1”. Claim 1 does not contain a limitation “a linear nucleic acid molecule”.

B) Claim 54 is indefinite over the recitation of “a nucleic acid comprising at least two components selected from the group consisting of a nucleic acid molecule engineered to comprise all or a portion of at least two Ter-sites, one or more ter-binding protein, one or more nucleotides, one or more DNA polymerases, one or more reverse transcriptases, one or more suitable buffers, one or more primers, instructions, and one or more terminating agents” (emphasis added). It is not clear how a nucleic acid can comprises proteins, buffers or instructions.

#### ***Claim Rejections - 35 USC § 102***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1, 3-6 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Lee et al. (J. Biol. Chem., vol. 267, pp. 8778-8784, 1992) and evidenced by Bussiere et al. (Mol. Microbiol., vol. 31, pp. 1611-1618; cited in the IDS).

Regarding claim 1, Lee et al. teach an isolated nucleic acid molecule engineered to comprise two Ter-sites (plasmid oriC-terCW.CCW). The nucleic acid comprises an origin of replication. The Ter sites are arranged with respect to the origin of replication in such a way that the sequence between the Ter sites which does not contain the origin of replication is not replicated in cells expressing a replication termination protein (Fig. 1 (c); Fig. 2, 3).

Regarding claim 3, Lee et al. teach TerB sites (Fig. 1 (c)).

Regarding claim 4, Lee et al. teach plasmids (Fig. 1 (c)).

Regarding claim 5, Lee et al. teach a linear molecule comprising the Ter sites capable of being bound by a Ter-binding protein (Fig. 4 (a)).

Regarding claim 6, Lee et al. teach plasmids comprising restriction enzyme recognition sequences (Fig. 1 (c)).

Regarding claim 34, Lee et al. teach composition comprising plasmid oriC-terCW.CCW and Ter-binding protein (page 8778, the last paragraph, continued on page 8779; Fig. 3).

Regarding claim 35, Lee et al. teach ter-binding protein (TBP) from *E. coli* (page 8779, first full paragraph). Lee et al. do not use the term “Tus” for this protein. Bussiere et al. teach that the ter-binding protein of *E. coli* is Tus (page 1615, fourth paragraph). Therefore, Lee et al. teach Tus protein.

11. Claims 13 and 14 are rejected under 35 U.S.C. 102(a) as being anticipated by Neylon et al. (Biochemistry, vol. 39, pp. 11989-11999, October 2000; cited in the IDS) as evidenced by Jonsson et al. (Biotechniques, vol. 11, pp. 620-627, 1991).

Regarding claims 13 and 14, Neylon et al. teach a solid support (BIACORE chip) comprising oligonucleotides comprising Ter sites (page 11990, second paragraph; Table 2).

Neylon et al. do not specifically teach that the solid support is a non-biological material. However, as evidenced by Jonsson et al., the BIACORE chip consists of glass support coated with gold film, therefore the solid support a non-biological material.

12. Claim 54 is rejected under 35 U.S.C. 102(b) as being anticipated by Perkin Elmer Cetus (October 1988).

For the purpose of this rejection the kit claimed is considered to comprise at least two components selected from the group consisting of a nucleic acid molecule engineered to comprise all or a portion of at least two Ter-sites, one or more Ter-binding protein, one or more nucleotides, one or more DNA polymerases, one or more reverse transcriptases, one or more suitable buffers, one or more primers, instructions, and one or more terminating agents.

Perkin Elmer Cetus teach a GeneAmp DNA Amplification Reagent Kit consisting of Taq DNA polymerase, four nucleotides, a reaction buffer, two primers and instructions.

***Claim Rejections - 35 USC § 103***

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neylon et al. and Gold et al. (U.S. Patent No. 6,242,246).

A) Claim 15 is drawn to a solid support of claim 13 wherein the oligonucleotide is capable of forming a stem-loop or hairpin, and claim 16 is drawn to a solid support of claim 15, where a duplex portion of the stem-loop or hairpin comprises a Ter-site.

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B) Neylon et al. teaches an assay which includes binding of Tus to double-stranded Ter sites, but also to single stranded DNA and non-specific sequences. Neylon et al. do not teach oligonucleotides capable of forming stem-loop or hairpin or oligonucleotides with the Ter-sites in the duplex portion of the stem-loop or hairpin.

C) Gold et al. teach solid support with stem-loop nucleic acid molecules which can bind target molecules, such as proteins (col. 4, lines 33-36; Fig. 6; col. 14, lines 26-67;

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to have used the hairpin nucleic acids of Gold et al. in the assays of Neylon et al. The motivation to do so would have been that using hairpin nucleic acids allowed detection of binding to single-stranded (loop of the stem-loop or hairpin) and double-stranded (stem of the stem-loop or hairpin) nucleic acids utilizing single nucleic acid molecules.

15. No claims are allowed.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teresa E Strzelecka whose telephone number is (703) 306-5877. The examiner can normally be reached on M-F (8:30-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

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TS

August 1, 2003

TS



**BJ FORMAN, PH.D.**  
**PRIMARY EXAMINER**